IS 15550 (2005): Failure mode effects analysis [MSD 3: Statistical Methods for Quality and Reliability]

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Indian Standard

FAILURE MODE EFFECTS ANALYSIS

ICS 03.120.30

BUREAU OF INDIAN STANDARDS
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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Statistical Methods for Quality and Reliability Sectional Committee, had been approved by the Management and Systems Division Council.

FMEA is a problem prevention technique of identifying or investigating potential failure modes and related causes. It can be:

a) applied in early concept selection or design phase and then progressively refined and updated as the design evolves.
b) used to recognize and evaluate the potential failure of a product/process and its effects.
c) helpful in identification of all possible causes, including root causes in some cases, and also helpful in establishing the relationships between causes.
d) used as a tool to aid in the improvement of the design of any given product or process.
e) used to document the process.

It is one of the method of reliability analysis intended to identify failures having significant consequences on the system performance in the application considered.

Starting from the basic element failure characteristics and the functional system structure, the FMEA determines the relationship between the element failures and the system failures, malfunctions, operational constraints, degradation of performance or integrity. To evaluate in addition to primary component failures, secondary and higher order system and sub-system failures, sequence of events in time may have to be considered.

The FMECA is composed of two complementary analyses, one is FMEA and the other is CA (Criticality Analysis). In the FMECA (Failure Modes, Effects and Criticality Analysis) there is assessment related to the failure modes severity and probability of occurrence.

The composition of the Committee responsible for the formulation of this standard is given in Annex R.

Indian Standard

FAILURE MODE EFFECTS ANALYSIS

1 SCOPE

1.1 This standard describes potential Failure Mode and Effects Analysis (FMEA) and provides generic guidelines in the application of the technique. There are four basic types of FMEA, namely:

a) Design FMEA,
b) Process FMEA,
c) Programme/Project FMEA, and
d) Machinery FMEA.

1.2 Process FMEA is of two types:

a) Manufacturing FMEA, and
b) Assembly FMEA.

The Machinery and Programme FMEA are not covered by this standard. FMEA includes all requirements of FMECA as well. The typical Design FMEA and Process FMEA Quality Objectives are listed in Annex A and Annex B.

2 REFERENCES

The following standards contain provisions, which through reference in this text constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

IS No.	*Title*
11137 (Part 2) : 1984	Analysis technique for system reliability: Part 2 Procedures for failure mode and effects analysis (FMEA) and failure mode effects and criticality analysis (FMECA)
10645 : 2003	Methods of estimation of process capability and process performance
15280 : 2002	Quality function deployment

3 TERMINOLOGY

3.1 FMEA — FMEA is an analytical technique that combines the technology and experience of several engineering disciplines in identifying foreseeable failure modes of a product or process and planning for its elimination or reduction in the likelihood of the potential failure occurring. It is like defining what a design or process must do to satisfy the customer.

3.1.1 *Design FMEA* — Design FMEA concentrates effort on product itself, that is product design and development, components/parts/sub-systems/systems used based on design tolerance specified causing catastrophic or critical failure.

3.1.2 *System FMEA* — System FMEA can be considered to be made up of various sub-systems. The focus is to ensure that all interfaces and interactions are covered among various sub-systems that make up the system as well as interfaces to other product systems and the customer. Interfaces and interactions as well as items, functions and failure modes examples are shown in Annex C.

3.1.3 *Sub-system FMEA* — Subsystem FMEA focus is to ensure that all interfaces and interactions are covered among the various components that make up the subsystem.

3.1.4 *Component FMEA* — Component FMEA is generally an FMEA focused on the sub-set of a sub-system.

3.1.5 *Process FMEA* — Process FMEA concentrates effort on manufacturing process with which the product gets built.

3.1.6 *Manufacturing FMEA* — In manufacturing FMEA's, the failure modes are generally dimensional or visual.

3.1.7 *Assembly FMEA* — In assembly FMEA's, the failure modes are generally relational dimensions, missing parts, parts assembled incorrectly.

3.1.8 *Programme/Project FMEA* — Programme/ Project FMEA concentrates effort on resolving programme/project or workgroup problems.

3.1.9 *Machinery FMEA* — A machinery FMEA for tooling and equipment is utilized for addressing potential failure modes and their associated causes/ mechanisms.

3.2 Function — A function could be any intended purpose of a product or process. FMEA functions are best described in verb-noun format with engineering specifications for example, delivery valve spring controls unloading (inline Fuel Injection pump), assemble flywheel to engine, ream hole and fill in order form) Fuel Injection.

3.3 Potential Failure Modes — A potential failure

Mode describes the way in which a product or process could fail to perform its desired function (design intent or performance requirements) as described by the needs, wants and expectations of the internal and external customers (for example, fatigue/erosion/wear, flywheel not perpendicular to crank, hole oversized, wrong information used).

3.4 Potential Effect(s) of Failure — The effects of the failure mode on the function, as perceived by the customer. The customer could be: the next operation, the assembly line, and the end user (for example, loss of engine performance, smoke, engine vibration, oil leakage, delay in processing).

3.5 Severity (*S*) — Severity is an assessment of how serious the effect of the potential Failure Mode is on the customer.

3.6 Classification — Classify any special product or process characteristics (for example, critical, key, major, significant) for components, sub-systems, or systems that may require additional design or process controls.

3.7 Potential Causes/Mechanisms of Failure — A cause is the means by which a particular element of the design or process results in a failure mode (for example, hydraulic duty, dirt on crank flange, bushings worn on spindle, catalog information incorrect).

3.8 Occurrence (*O*) — Occurrence is the assessment of likelihood that a particular cause will happen and result in the failure mode during the intended life and use of the product. It is how frequently the specific failure cause/mechanism is projected to occur.

3.9 Current Controls (Prevention, Detection) — Current Controls (design and process) are the mechanisms that prevent the cause of the failure mode from occurring, or which detect the failure before it reaches the customer (for example, fail-safing used for flywheel assembly, SPC used to monitor hole size, a cross checking by a printing company).

3.10 Detection (*D*) — Detection is an assessment of the likelihood that the current controls (applicable) will detect the cause of the failure mode or the failure mode itself, thus preventing it from reaching the customer.

3.11 Risk Priority Number (*RPN*) — The Risk Priority Number is the mathematical product of the numerical Severity (*S*), Occurrence (*O*), and Detection (*D*) ratings. $RPN = (S) \times (O) \times (D)$. This number can be used to rank order the concerns in the design/process requiring additional quality planning.

3.12 Recommended Actions — Engineering assessment for preventive/corrective action should be first directed at high severity, high *RPN*, and other items designated by the team. The intent of any recommended action is to reduce rankings in the following order: Severity, Occurrence and Detection.

3.13 Responsibility for the Recommended Actions — Specify departments and individuals responsible for each recommendation with target date.

3.14 Actions Taken — Brief description of the actual action and effective date.

3.15 Revised Ratings — After the preventive/ corrective action has been taken, estimate and record resulting Severity, Occurrence and Detection ratings. Calculate and record resulting *RPN*. All revised ratings should be reviewed for further necessary actions.

4 GENERAL

4.1 Purpose

The primary objective of FMEA is to improve the design of the product and/or process that is being analyzed. Higher risk failure modes are identified through the analysis, and their effects are either eliminated or mitigated by recommending design, process and allied improvements.

4.2 Application

FMEA's are generally done where a level of risk is anticipated in a programme early in product or process development. Some of the factors considered in deciding to do FMEA's are: new technology, new processes, new designs, or changes in the environment, loads, or regulations. FMEA's can be done on components or systems that make up products, processes or manufacturing equipment. They can also be done on software systems and processes involved in service industry.

4.3 Key Elements

The FMEA analysis generally follows these steps:

a) Identification of how the component of system or part of the process should perform;

b) Identification of potential failure modes, effects and causes;

c) Identification of risk related to failure modes and effects;

d) Identification of recommended actions to eliminate or reduce the risk;

e) Follow up actions to close out the recommended actions; and

f) Documentation and archiving.

The analysis must be completed in time for the recommended actions to be implemented into the final design or process.

The FMEA to be revisited through product life cycle and on changes in product or process design.

NOTE — A generic flow chart for FMEA Process is included in Annex D.

5 DEVELOPMENT OF A DESIGN FMEA

5.1 The process of preparing the design FMEA begins with listing the design intent. Customer needs and wants determined from Quality Function Deployment (QFD) (*see* IS 15280), product requirements, and/or manufacturing/assembly/service/recycling requirements should be incorporated. The steps in preparation of design FMEA includes:

a) Define the part/sub-system/system to be analyzed;
b) Obtain Equipment and Material requirements;
c) Select FMEA team members;
d) Identify information that may be needed such as: drawings, sketches, standards, layouts, system structure, system environment, system initiation, operation, control and maintenance etc;
e) Plan what will be done with the results; such as who will coordinate the action plan; and
f) Schedule first meeting.

5.2 A design FMEA should begin with a block diagram for the system, sub-system, and/or component being analyzed. Examples of block diagrams are shown in Annex E, F and G.

5.3 A blank design FMEA form that may be used for documentation of the analysis of potential failures and their effects is available in Annex H.

5.4 An example of a completed form is contained in Annex J. The necessary header information may be recorded indicated as below:

a) *FMEA Number* — Enter document number used for tracking.
b) *Item* — Enter the name of system, sub-system, or component for which the design is being analyzed.
c) *Design Responsibility* — Enter the Original Equipment Manufacturer (OEM), department and group. Also include the supplier name, if applicable.
d) *Prepared by* — Enter the name, telephone number and company of the engineer responsible for preparing the FMEA.
e) *Model Year(s)/Programme(s)* — Enter the intended model year(s)/programme(s) that will use and/or be affected by the design being analyzed (if known).
f) *Key Date* — Enter the initial FMEA due date, which should not exceed the scheduled production design release date.
g) *FMEA Date* — Enter the date, the original FMEA was compiled and the latest revision date.
h) *Core Team* — List the names of the responsible individuals and departments.

6 THE DESIGN FMEA PROCESS

FMEA Process Sequence is shown in Annex K.

6.1 Identify Functions

Enter as concisely as possible, the function of the item being analyzed to meet the design intent. Include information (metrics measurable) regarding the environment in which this system operates. If the item has more than one function with different potential modes of failure, list all the functions separately.

6.2 Identify Potential Failure Modes

List each potential failure mode associated with the particular item and item function. The assumption is made that the failure could occur but may not necessarily occur. Potential failure modes that could occur only under certain operating and usage conditions should be considered. Typical failure modes examples may include:

> Premature operation, Failure to operate at a prescribed time, Failure to cease operation at a prescribed time, Failure during operation, Cracked, Loosened, Sticking, Fractured, Slips (does not hold full torque), Inadequate support, Disengages too fast, Intermittent signal, Deformed, Leaking, Oxidized, Does not transmit torque, No support (structural), Harsh engagement, Inadequate signal, No signal, Drift.

6.3 Identify Potential Effects of Failure

Describe the effects of the failure in terms of what the customer (internal or external) might notice or experience. State clearly if the failure mode could impact safety or non-compliance to regulations. The effects should always be stated in terms of specific system, sub-system or component being analyzed. A hierarchical relationship exists between component, sub-system and system levels. Typical failure effects may include:

> Noise, Erratic operation, Poor appearance, Unstable, Intermittent operation, Leaks, Rough, Inoperative, Unpleasant odour, Operation impaired, Thermal event, Regulatory non-compliance.

6.4 A failure effect may also impact the next higher level and ultimately may affect the highest level under analysis. Therefore the failure effects on each higher level should be evaluated.

6.5 Determine Severity (*S*)

Severity is the rank associated with the most serious effect for a given failure mode. Severity is a relative ranking within the scope of the individual FMEA. A reduction in the severity ranking can be effected only through a design change. Suggested severity are given in Table 1.

6.6 Identify Special Characteristics (Classification)

Identify special characteristics requiring additional design or process controls at system, sub-system and component level using standardized appropriate symbols for critical, key, major, significant characteristics.

6.7 Identify Possible Causes/Mechanisms of Failure

List concisely and completely every potential cause and/or failure mechanism for each failure mode so that remedial efforts can be aimed at pertinent causes. Typical failure causes may include:

> Incorrect material specified, Inadequate design life assumption, Over-stressing, Insufficient lubrication capability, Inadequate maintenance instructions, Incorrect algorithm, Improper software specification, Improper surface finish specification, Inadequate travel specification, Improper friction material specified, Excessive heat, Improper tolerance specified.

Typical failure mechanisms may include:

> Yield, Fatigue, Material instability, Creep, Wear, Corrosion, Chemical oxidization, Electro migration.

6.8 Determine Occurrence (*O*)

Occurrence is the likelihood that specific cause/ mechanism will occur during the design life. It has a relative meaning rather than an absolute value. Preventing or controlling the causes/mechanisms of the failure mode through a design change or design process change is the only way a reduction in occurrence ranking can be effected. Occurrence can be estimated using Table 2.

6.9 Identify Current Design Controls

List the prevention, design validation/verification, or other activities that have been completed or committed to and that will assure the design adequacy for the failure mode and/or cause/mechanism under consideration. Typical current controls may include:

> Design reviews, Fail/Safe designs such as pressure relief valve, Mathematical studies, Rig/ Lab testing, Feasibility review, Prototype tests, Road testing, Fleet testing.

6.9.1 There are two types of design controls to consider:

Table 1 Suggested Design FMEA Severity Evaluation Criteria

(*Clause* 6.5)

Effect	Criteria: Severity of Effect	Ranking
(1)	(2)	(3)
Hazardous without warning	Very high severity ranking when a potential failure mode affects safe item operation and/or involves non-compliance with Government regulation without warning	10
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe item operation and/or involves non-compliance with Government regulation with warning	9
Very High	Item inoperable (loss of primary function)	8
High	Item operable but at reduced level of performance. Customer very dissatisfied	7
Moderate	Item operable but comfort/convenience item(s) inoperable customer dissatisfied	6
Low	Item operable convenience/convenience item(s) operable at a reduced level of performance. Customer somewhat dissatisfied	5
Very Low	Fit and Finish? Noise and vibration item does not conform. Defect noticed by most customers (greater than 75 percent)	4
Minor	Fit and Finish? Noise and vibration item does not conform. Defect noticed by about 50 percent of customers	3
Very Minor	Fit and Finish? Noise and vibration item does not conform. Defect noticed by discriminating customers (less than 25 percent)	2
None	No discernible effect	1

NOTES

1 Making design revisions that compensate or mitigate the resultant severity of failure can sometimes reduce high severity rankings. For example "seat belts" can mitigate the severity of a vehicle crash.

2 Ranking tables for *SOD* (Severity, Occurrence and Detection in Tables 1, 2 and 3) given in this standard are most appropriate for use in Automotive Industry. Similar ranking scales can be developed or formed on similar lines or found in published literature for FMEA specific to other industries.

Table 2 Suggested Design FMEA Occurrence Evaluation Criteria

(*Clause* 6.8)

Probability of Failure	Possible Failure Rates per Million Items	Ranking
(1)	(2)	(3)
Very High: Persistent failures	$> 10^5$ items	10
	5×10^4 items	9
High: Frequent failures	2×10^4 items	8
	10^4 items	7
Moderate: Occasional failures	5×10^3 items	6
	2×10^3 items	5
	10^3 items	4
Low: Relatively few failures	5×10^2 items	3
	10^2 items	2
Remote: Failure is unlikely	≤ 10 items	1

a) *Prevention*: Prevent the cause/mechanism of failure or the failure mode from occurring, or reduce their rate of occurrence.

b) *Detection*: Detect the cause/mechanism of failure or the failure mode, either by analytical or physical methods, before the item is released for production.

The preferred approach is to first use prevention controls. Once the design controls have been identified, review all prevention controls to determine if any occurrence rankings need to be revised.

6.10 Determine Detection (*D*)

Detection is the rank associated with the best detection control listed in the design control. Detection is a relative ranking within the scope of the individual FMEA. In order to achieve a lower ranking generally the planned design control has to improve. Detection can be estimated using Table 3.

After making the detection ranking, the team should review the occurrence ranking for still being appropriate.

6.11 Determine Risk Priority Number (RPN)

$$RPN = (S) \times (O) \times (D)$$

Within the scope of the individual FMEA this value (between 1 and 1 000) can be used to rank order the concerns in design.

Table 3 Suggested Design FMEA Detection Evaluation Criteria

(*Clause* 6.10)

Detection	Criteria: Likelihood of Detection by Design Control	Ranking
(1)	(2)	(3)
Absolute Uncertainty	Design control will not and/or can not detect a potential cause/mechanism and subsequent failure mode; or there is no design control	10
Very Remote	Very remote chance the design control will detect a potential cause/mechanism and subsequent failure mode	9
Remote	Remote chance the design control will detect a potential cause/mechanism and subsequent failure mode	8
Very Low	Very low chance the design control will detect a potential cause/mechanism and subsequent failure mode	7
Low	Low chance the design control will detect a potential cause/mechanism and subsequent failure mode	6
Moderate	Moderate chance the design control will detect a potential cause/mechanism and subsequent failure mode	5
Moderately High	Moderately high chance the design control will detect a potential cause/mechanism and subsequent failure mode	4
High	High chance the design control will detect a potential cause/mechanism and subsequent failure mode	3
Very High	Very high chance the design control will detect a potential cause/mechanism and subsequent failure mode	2
Almost Certain	Design control will almost certainly detect a potential cause/mechanism and subsequent failure mode	1

6.12 Take Actions to Reduce Risk

6.12.1 After special attention has been given to severity rankings of 9 or 10, the team then addresses other failure modes, with the intent of reducing severity, then occurrence, and then detection. The primary objective of recommended action is to reduce risks and increase customer satisfaction by improving the design.

6.12.2 Only a design revision can bring about a reduction in the severity ranking. Only removing or controlling one or more of the causes/mechanisms of the failure mode through a design revision can effect a reduction in the occurrence ranking. An increase in design validation/verification actions will result in a reduction in the detection ranking only.

6.13 Responsibility and Target Completion Date

Responsibility for recommended actions and target dates for completion must be indicated.

6.14 Actions Taken

List down the specific actions taken.

6.15 Calculate Revised *RPN* for Action Results

After the preventive/corrective actions are taken, estimate and record the resulting severity, occurrence and detection rankings. Calculate and record the resulting *RPN*. If no actions are taken, leave the related ranking columns blank.

6.16 Follow-Up Actions

The FMEA should always reflect the latest design level as well as the latest relevant actions, including those occurring after start of production. All recommended actions should be implemented or adequately addressed.

7 DEVELOPMENT OF A PROCESS FMEA

7.1 The process of preparing the process FMEA begins with listing process functions and requirements (process intent) for the line/process to be analyzed. The steps in preparation of system FMEA are:

a) Obtain equipment and material requirements;
b) Select FMEA team members;
c) Identify information that may be needed such as: drawings, sketches, standards, layouts, etc.;
d) Plan what will be done with the results, such as who will coordinate the action plan; and
e) Schedule first meeting.

It should begin with a flow chart of the process it addresses potential product and process related failure modes by specifying possibilities, quantifying risk, preventing/removing high-risk causes and re-evaluation of risk. The process FMEA does not rely on product design changes to overcome weakness in the process.

A blank process FMEA form that may be used for documentation of the analysis of potential failures and their effects is given in Annex L.

An example of a completed form is given in Annex M including numbered headings for ease of reference. The necessary header information may be recorded as below.

7.2 FMEA Number

Enter document number used for tracking.

7.3 Item

Enter the name of system, subsystem, or component for which the process is being analyzed.

7.4 Process Responsibility

Enter the Original Equipment Manufacturer (OEM), department and group. Also include the supplier name if applicable.

7.5 Prepared By

Enter the name, telephone number and company of the engineer responsible for preparing the FMEA.

7.6 Model Year(s)/Programme(s)

Enter the intended model year(s)/programme(s) that will use and/or be affected by the design/process being analyzed (if known).

7.7 Key Date

Enter the initial FMEA due date, which should not exceed the scheduled production date.

7.8 FMEA Date

Enter the date the original FMEA was compiled and the latest revision date.

7.9 Core Team

List the names of the responsible individuals and departments.

8 PROCESS OF DOING PROCESS FMEA

FMEA process sequence is given in Annex K.

8.1 Identify Function/Requirements

Enter a simple description of the process or operation being analyzed. Where the process involves numerous operations (for example, assembling) with different potential modes of failure, it may be desirable to list the operations as separate elements.

8.2 Identify Potential Failure Modes

It is a description of the non-conformance at that

specific operation. It can be a cause associated with a potential failure mode in a subsequent (downstream) operation or an effect associated with a potential failure in a previous (upstream) operation. Assume that the failure could occur but may not necessarily occur. Typical failure modes may include:

Bent, Cracked, Handling damage, Surface too rough, Open circuited, Burred, Hole too shallow, Dirty, Deformed, Short circuited, Hole off-location, Hole missing, Hole too deep, Surface too smooth, Mislabelled

NOTE — Potential failure modes should be described in 'physical' or technical terms, not as a symptom noticeable by the customer.

8.3 Identify Potential Effect(s) of Failure

8.3.1 Describe the effects of the failure in terms of what the customer might notice or experience. Customer may be an internal/external. Effects should always be stated in terms of product or system performance or process operation performance. Typical potential effect (s) of failure for the end user should always be stated in terms of product or system performance such as:

Noise, Erratic operation, Poor appearance, Unstable, Intermittent operation, Leaks, Rough, Inoperative, Unpleasant odour, Operation impaired, Degree of effort, Reworks/Repairs, Scrap, Draft, Excessive, Customer dissatisfaction

8.3.2 If the customer is the next operation or subsequent operations/locations, the effects should be stated in terms of process/operation performance such as:

Cannot fasten, Cannot bore/tap, Cannot mount, Cannot face, Damages equipment, Does not fit, Does not connect, Does not match, Causes excessive tool wear, endangers operator.

8.3.3 *Determine Severity (S)*

Severity is the rank associated with the most serious effect for a given failure mode. Severity is a relative ranking within the scope of the individual FMEA. A reduction in the severity ranking can be effected only through a design change to system, sub-system or component, or a re-design of the process. Severity can be estimated using Table 4.

8.3.4 *Identify Special Characteristics (Classification)*

Identify special product or process characteristics requiring additional process controls at system, sub-system and component level using standardized appropriate symbols for critical, key, major, significant minor characteristics. If a classification is identified in the process FMEA, notify the responsible design engineer since this may affect the engineering documents concerning control item identification.

8.3.5 *Identify Possible Causes/Mechanisms of Failure*

List concisely and completely every potential cause and/or failure mechanism for each failure mode so that remedial efforts can be aimed at pertinent causes. Typical failure causes may include:

Improper torque-over/under, Improper weld, Inaccurate gauging, Improper heat-treatment, Inadequate gating/venting, Inadequate or no lubrication, Part missing or mis-located, Worn locator, Broken tool, Worn tool, Chip on locator, Improper machine set-up.

8.3.6 *Improper Programming*

Only specific errors or malfunctions (for example, operator fails to install seal) should be listed; ambiguous phrases (for example, operator error, machine malfunction) should not be used.

8.3.7 *Determine Occurrence (O)*

Occurrence is the likelihood that specific cause/mechanism will occur. It has a relative meaning rather than an absolute value. Preventing or controlling the causes/mechanisms of the failure mode through a design change or design process change is the only way a reduction in occurrence ranking can be effected. Occurrence can be estimated using Table 5.

8.3.8 *Identify Current Process Controls*

List the process controls such as error/mistake proofing, statistical process control (SPC), or post process evaluation. The evaluation may occur at the subject operation or at subsequent operations. There are two types of process controls to consider:

Prevention: Prevent the cause/mechanism of failure or the failure mode from occurring, or reduce their rate of occurrence.

Detection: Detect the cause/mechanism of failure or the failure mode, and lead to corrective action(s).

The preferred approach is to first use prevention controls. Once the design controls have been identified, review all prevention controls to determine if any occurrence rankings need to be revised.

8.3.9 *Determine Detection (D)*

Detection is the rank associated with the best detection control listed in the process control. Detection is a relative ranking within the scope of the individual FMEA. In order to achieve a lower ranking generally the planned process control has to be improved. Detection can be estimated using Table 6.

Inspection Types — A: Error Proofed, B: Gauging, C: Manual Inspection.

After making the detection ranking, the team should review the occurrence ranking for still being appropriate.

Table 4 Suggested Process FMEA Severity Evaluation Criteria

(*Clause* 8.3.3)

Effect	Criteria: Severity of Effect (Customer Effect)	Criteria: Severity of Effect Manufacturing/Assembly Effect	Ranking
(1)	(2)	(3)	(4)
Hazardous without warning	Very high severity ranking when a potential failure mode affects safe item operation and/or involves noncompliance with Government regulation without warning	May endanger operator without warning	10
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe item operation and/or involves non-compliance with Government regulation with warning	May endanger operator with warning	9
Very High	Item inoperable (loss of primary function)	100 percent of product may have to be scrapped, or vehicle/item repaired with a repair time greater than one hour	8
High	Item operable but at a reduced level of performance. Customers very dissatisfied	Product may have to be sorted and a portion scrapped, or vehicle/item repaired with a repair time between a half hour and an hour	7
Moderate	Item operable but comfort/convenience item(s) inoperable. Customers dissatisfied	A portion of the product may have to be scrapped with no sorting, or item repaired with a repair time less than a half hour	6
Low	Item operable but comfort/convenience item(s) operable at a reduced level of performance	100 percent of product may have to be reworked, or item repaired off line	5
Very Low	Fit and Finish/Noise and vibration item does not conform. Defect noticed by most customers (greater than 75 percent)	The product may have to be sorted, with no scrap, and a portion reworked	4
Minor	Fit and Finish/Noise and vibration item does not conform. Defect noticed by 50 percent of customers	A portion of the product may have to be reworked, with no scrap, on-line but out of station	3
Very Minor	Fit and Finish/Noise and vibration item does not conform. Defect noticed by discriminating customers (less than 25 percent)	A portion of the product may have to be reworked, with no scrap, on-line but in station	2
None	No discernible effect	Slight inconvenience to operation or operator, or no effect	1

NOTE — Ranking tables for *SOD* (Severity, Occurrence and Detection in Tables 4, 5 and 6) given in this standard are most appropriate for use in Automotive Industry. Similar ranking scales can be developed or formed on similar lines or found in published literature for FMEA specific to other industries.

Table 5 Suggested Process FMEA Occurrence Evaluation Criteria

(*Clause* 8.3.7)

Probability of Failure	Possible Failure Rates per Million Items	P_{pk}	Ranking
(1)	(2)	(3)	
Very High: Persistent failures	$> 10^5$ items	<0.55	10
	5×10^4 items	>0.55	9
High: Frequent failures	2×10^4 items	>0.78	8
	10^4 items	>0.86	7
Moderate: Occasional failures	5×10^3 items	>0.94	6
	2×10^3 items	>1.00	5
	10^3 items	>1.10	4
Low: Relatively few failures	5×10^2 items	>1.20	3
	10^2 items	>1.30	2
Remote: Failure is unlikely	$\leq$ 10 items	>1.67	1

NOTE — For P_{pk}, *see* IS 10645.

Table 6 Detection Methods

(*Clause* 8.3.9)

Detection	Criteria	Inspection Types X			Suggested Range of Detection Methods	Ranking
		A	B	C		
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Almost Impossible	Absolute uncertainty of non-detection			X	Can not detect or is not checked	10
Very Remote	Controls will probably not detect			X	Control is achieved with indirect or random checks only	9
Remote	Controls have poor chance of detection			X	Control is achieved with visual inspection only	8
Very Low	Controls have poor chance of detection			X	Control is achieved with double visual inspection only	7
Low	Controls may detect		X	X	Control is achieved with charting methods, such as SPC (Statistical Process Control)	6
Moderate	Controls may detect		X		Control is based on variable gauging after parts have left the station, or Go/No Go gauging performed on 100 per-cent of the parts after parts have left the station	5
Moderately High	Controls have a good chance to detect	X	X		Error detection in subsequent operations, or gauging performed on set-up and first piece check (for set-up causes only)	4
High	Controls have a good chance to detect	X	X		Error detection in-station, or error detection in subsequent operations by multiple layers of acceptance: supply, select, install, verify. Cannot accept discrepant part	3
Very High	Controls almost certain to detect	X	X		Error detection in-station (automatic gauging with automatic stop feature). Cannot pass discrepant part	2
Very High	Controls almost certain to detect	X			Discrepant parts cannot be made because item has been error — proofed by process/product design	1

8.3.10 *Determine Risk Priority Number (RPN)*

$$RPN = (S) \times (O) \times (D)$$

Within the scope of the individual FMEA this value (between 1 and 1 000) can be used to rank order the concerns in process.

8.3.11 *Take Actions to Reduce Risk*

After special attention has been given to severity rankings of 9 or 10, the team then addresses other failure modes, with the intent of reducing severity, then occurrence, and then detection. The primary objective of recommended action is to reduce risks and increase customer satisfaction by improving the process.

Only a design and/or process revision can bring about a reduction in the severity ranking. A reduction in the occurrence ranking can be effected by process and/or design revisions. Error/Mistake proofing methods can be used for reduction in the detection ranking. Emphasis must, however, be placed on preventing defects rather than detecting them.

8.3.12 *Responsibility and Target Completion Date*

Responsibility for recommended actions and target dates for completion must be indicated.

8.3.13 *Actions Taken*

List down complete details of actions taken.

8.3.14 *Calculate Revised RPN for Action Results*

After the preventive/corrective actions are taken, estimate and record the resulting severity, occurrence and detection rankings. Calculate and record the resulting *RPN*. If no actions are taken, leave the related ranking columns blank.

8.3.15 *Follow-Up Actions*

The FMEA should always reflect the latest design level as well as the latest relevant actions, including those occurring after start of production. All recommended actions should be implemented or adequately addressed.

9 FMEA TIMING

FMEA is a living document. Annex N shows the timing of system/Design/Process FMEA in the product development cycle. FMEA need to be revisited and updated based on feedback from field usage and/or changes in the product/process design.

10 FMEA BENEFITS

a) The method is directed towards improving designs and processes by preventing potential failures (proactive approach).

b) Identifies and prioritizes areas of potential risk in the design or process.

c) Can serve as evidence of 'due care'.

d) Encourages multi-discipline participation in the analysis of designs and processes.

e) Provides input to various related activities, for example, analysis, test planning, process control planning, control plan etc.

f) Discloses safety hazard and liability problem areas, or non-compliance with regulatory requirements.

g) Facilitates or supports the determination of test criteria, test plans, diagnosis procedures, etc (for example, performance testing, reliability testing).

h) Identifies circuits for worst case analysis (failure modes involving parameter drifts frequently require worst case analysis).

11 FMEA LIMITATIONS

a) The method relies on estimations and predictions of the failure modes based on iterative opinions of participating members and their risk, in the absence of hard field data.

b) The time taken to do the analysis must be balanced with the benefits derived from the activity.

c) The results of human error are not usually included.

d) The consideration of effects of environment requires a thorough knowledge of the characteristics and performance of the different components of the system.

12 CHECKLISTS

Checklists for Design FMEA and Process FMEA are shown in Annex P and Annex Q.

ANNEX A

(*Clause* 1.2)

DESIGN FMEA QUALITY OBJECTIVES

A-1 DESIGN IMPROVEMENTS

The FMEA drives Design Improvements as the primary objective.

A-2 HIGH RISK FAILURE MODES

The FMEA address all high risk Failure Modes, as identified by the FMEA team, with executable Action Plans. All other failure modes from the Design FMEA.

A-3 A/D/V or DVP & R PLANS

The Analysis/Development/Validation (A/D/V), and/or Design Verification Plan and Report (DVP & R) considers the failure modes from the Design FMEA.

A-4 INTERFACES

The FMEA scope includes integration and interface failure modes in both block diagram and analysis.

A-5 LESSONS LEARNED

The FMEA considers all major 'lessons learned' (such as high warranty, campaigns, etc) as input to failure mode identification.

A-6 SPECIAL OR KEY CHARACTERISTICS

The FMEA identifies appropriate Key Characteristics candidates, as input to the Key Characteristics selection process, if applicable due to company policy.

A-7 TIMING

The FMEA is completed during the 'Window of opportunity' where it could most efficiently impact the product design.

A-8 TEAM

The right people participate as part of the FMEA team throughout the analysis, and are adequately trained in the procedure. As appropriate, a facilitator should be utilized.

A-9 DOCUMENTATION

The FMEA document is completely filled out 'by the book', including 'Action Taken' and new *RPN* values.

A-10 TIME USAGE

Time spent by the FMEA team, as early as possible, is an effective and efficient use of time, with a value-added result. This assumes Recommended Actions are identified as required and the actions are implemented.

NOTE — Specific programme requirements take precedence.

ANNEX B

(*Clause* 1.2)

PROCESS FMEA QUALITY OBJECTIVES

B-1 PROCESS IMPROVEMENTS

The FMEA drives Process Improvements as the primary objective, with an emphasis on Error/Mistake Proofing solutions.

B-2 HIGH RISK FAILURE MODES

The FMEA address all high risk Failure Modes, as identified by the FMEA team, with executable Action Plans. All other failure modes are considered.

B-3 PROCESS CONTROL PLAN

The Process Control Plan considers the failure modes from the Process FMEA.

B-4 INTEGRATION

The Process FMEA is integrated and consistent with the Process Flow Diagram and the Process Control Plan. The Process FMEA considers the Design FMEA as part of its analysis.

B-5 LESSONS LEARNED

The FMEA considers all major 'lessons learned' (such as high warranty campaigns, etc) as input to failure mode identification.

B-6 SPECIAL OR KEY CHARACTERISTICS

The FMEA identifies appropriate Key Characteristics candidates, as input to the Key Characteristics selection process.

B-7 TIMING

The FMEA is completed during the 'Window of opportunity' where it could most efficiently impact the product design of product or process.

B-8 TEAM

The right people participate as part of the FMEA team throughout the analysis, and are adequately trained in the procedure. As appropriate, a facilitator should be utilized.

B-9 DOCUMENTATION

The FMEA document is completely filled out 'by the book', including 'Action Taken' and new *RPN* values.

B-10 TIME USAGE

Time spent by the FMEA team, as early as possible, is an effective and efficient use of time, with a value-added result. This assumes Recommended Actions are identified as required and the actions are implemented.

NOTE — Specific programme requirements take precedence.

ANNEX C

(*Clause* 3.1.2)

SYSTEM FMEA

C-1 This Section discusses the scope of System, Subsystem, and Component FMEA's. To help illustrate the meaning of these FMEA's, two examples have been constructed in Fig. C1 (for Interfaces and Interactions) and in Fig. C2 (for Item, Function, and Failure Modes).

Example 1: Interfaces and Interactions

It is the responsibility of the FMEA Team to specify the scope of their respective FMEA's. The example in Fig. C1 shows that the Team has specified Subsystems A, B, C and D along with the surrounding environment as comprising the System that must be considered while completing the System FMEA.

Interfaces

Subsystems are directly connected via interfaces. In Fig. C1, Interfaces between subsystems are shown where Subsystem A touches (connects with) Subsystem B, B touches C, C touches D, A touches D, and B touches D. It should be noted that the Environment also touches each of the subsystems listed in Fig. C1, which requires that the 'Environmental Interfaces' be considered when completing the FMEA.

NOTE — Each Subsystem FMEA should have its Interfaces included in its respective Subsystem FMEA.

Interaction

A change in one subsystem might cause a change in another subsystem. In Figure C1, interactions between subsystems can occur between any of the interfacing systems (for example, Subsystem A heats up resulting in Subsystem D and Subsystem B also gaining heat

through the respective interfaces, as well as the Subsystem A giving off heat to the environment). Interactions might also occur between 'non-contacting' system via transfer through the 'environment' (for example, if the environment is composed of high humidity and Subsystem A and C are dissimilar metals separated by a non-metal composing Subsystem B, Subsystems A and C can still have an electrolytic reaction due to the moisture from the environment). Thus, interactions between non-contacting subsystems can be relatively difficult to predict, but are important and should be considered.

Example 2: Items, Functions, and Failure Modes

Figure C2 describes a method of showing the Items, Functions, and Failure Mode in a 'tree arrangement' that can assist the team in visualizing the System, Subsystems, and Components. At the System Level, the descriptions will tend to be much more general than for the Subsystems and Components (Components will usually have the most specific descriptions) The 'tree arrangement' is arranged as follows for the System, Subsystem, and Components.

Item

Design Objectives (a statement of design objectives is often helpful)

- FUNCTION 1
  - FAILURE MODE A
  - FAILURE MODE B
  - etc.....
- FUNCTION 2
  - FAILURE MODE A
  - FAILURE MODE B
  - etc.....
- etc.....

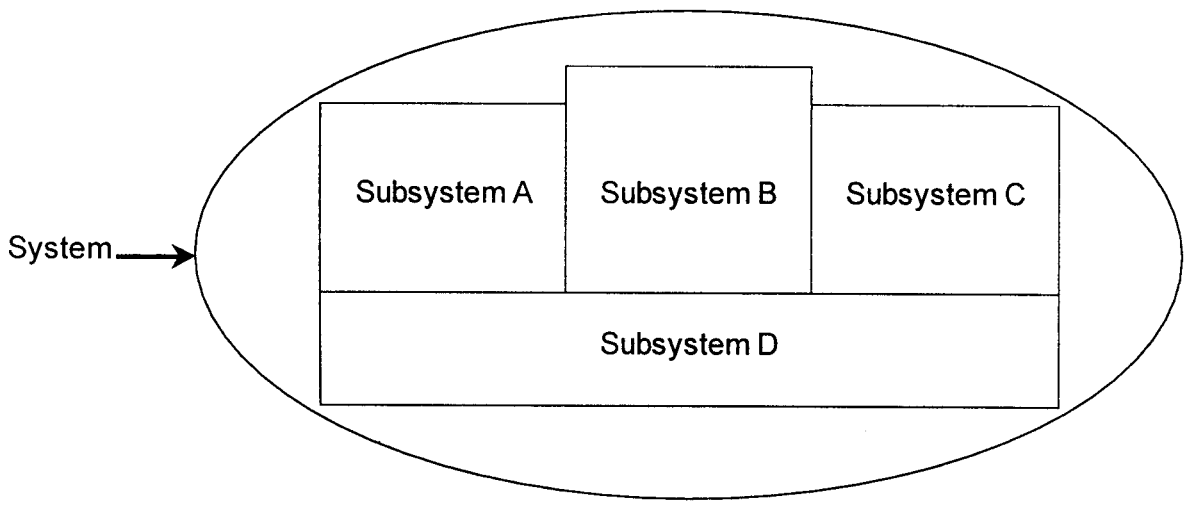


FIG. C1 INTERFACES AND INTERACTIONS

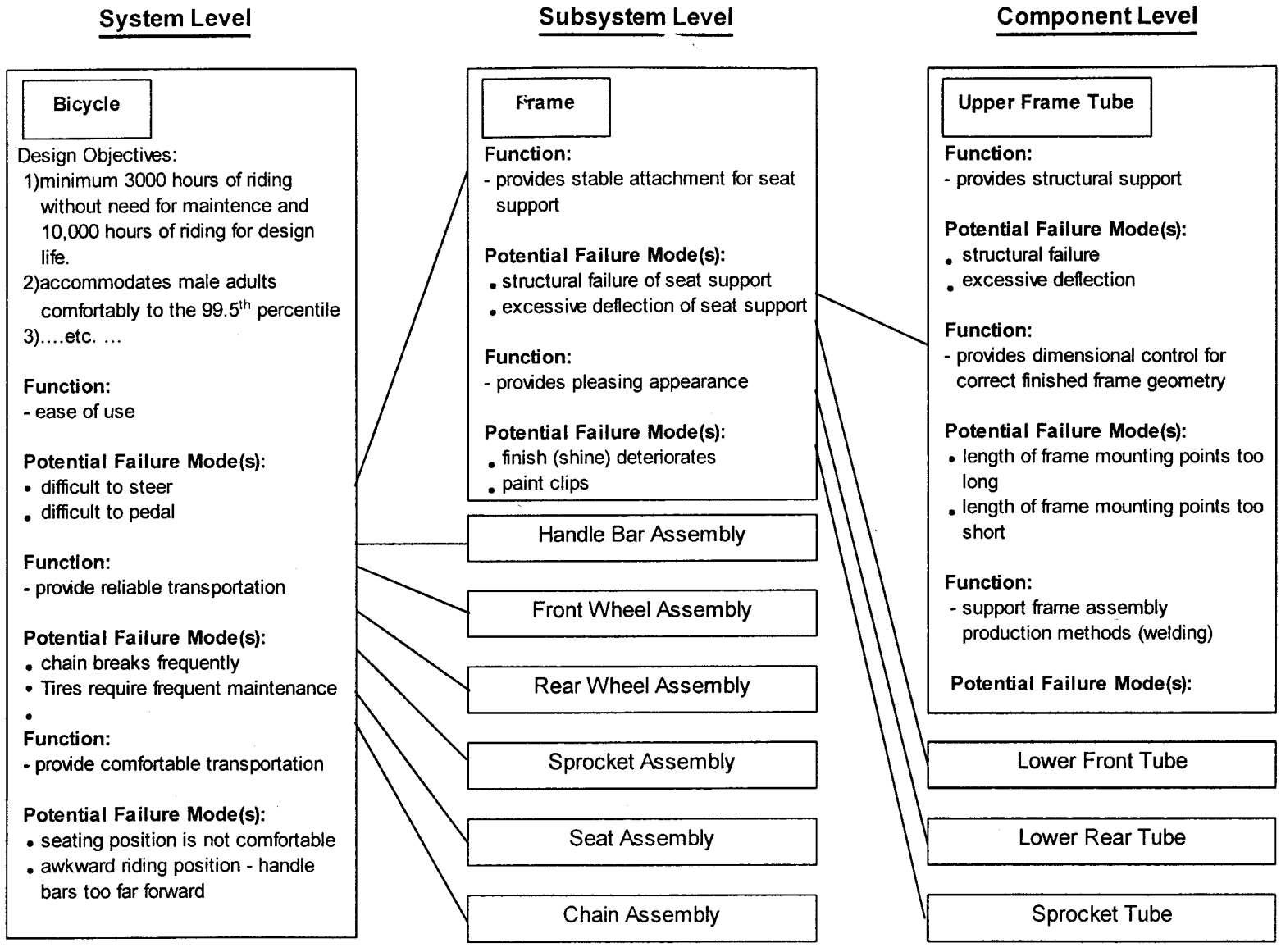
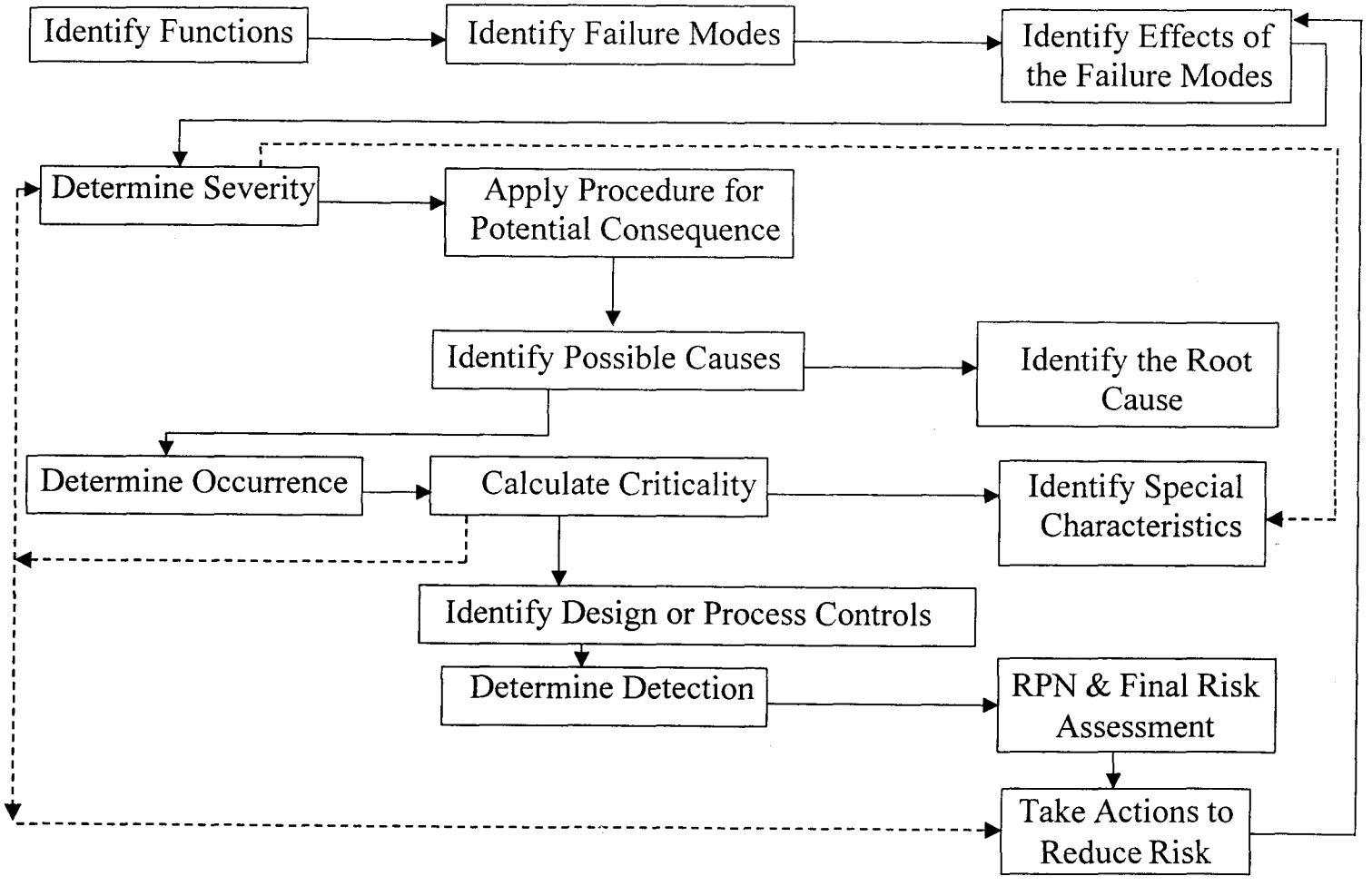


FIG. C2 ITEMS, FUNCTIONS AND FAILURES

ANNEX D

(*Clause* 4.3)

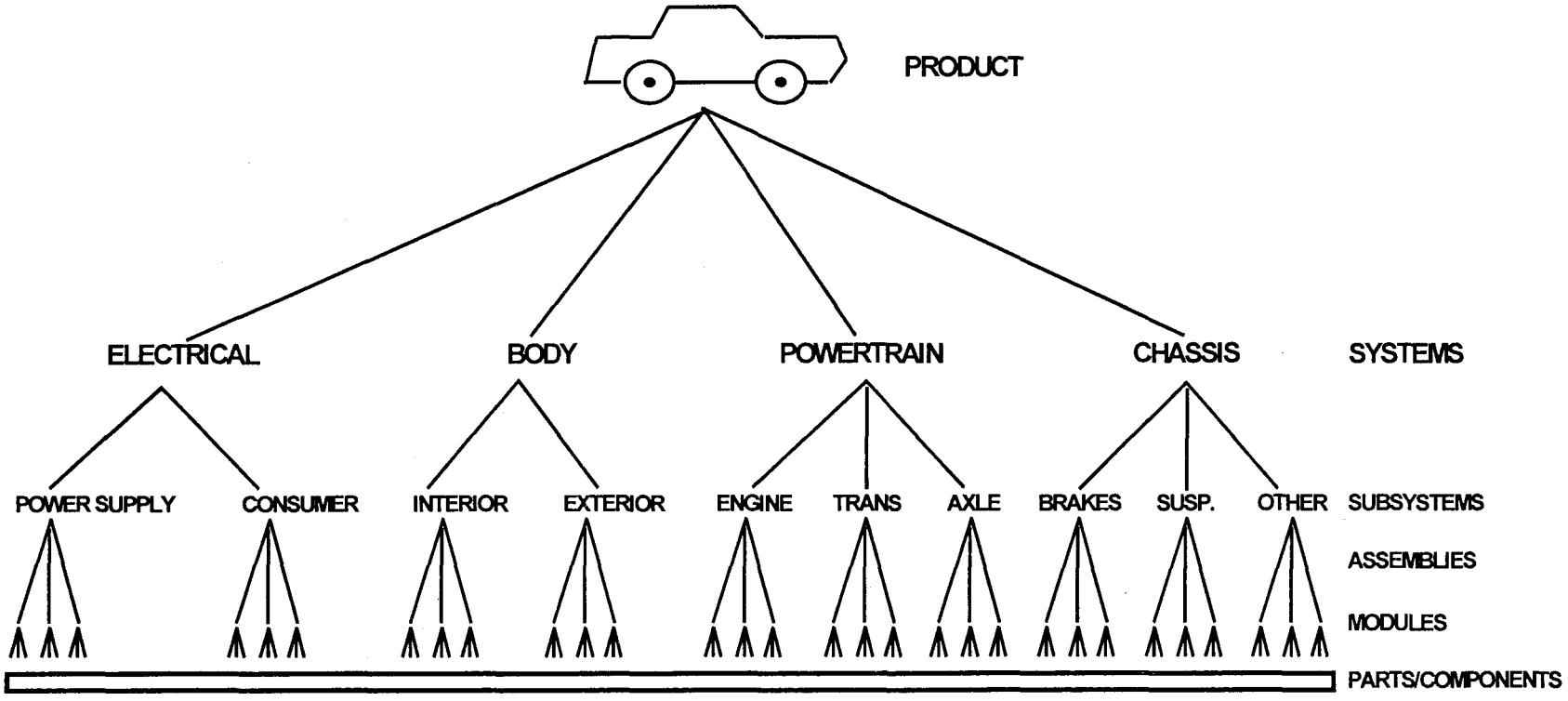
THE FMEA PROCESS



ANNEX E

(*Clause* 5.2)

HIERARCHY DIAGRAM

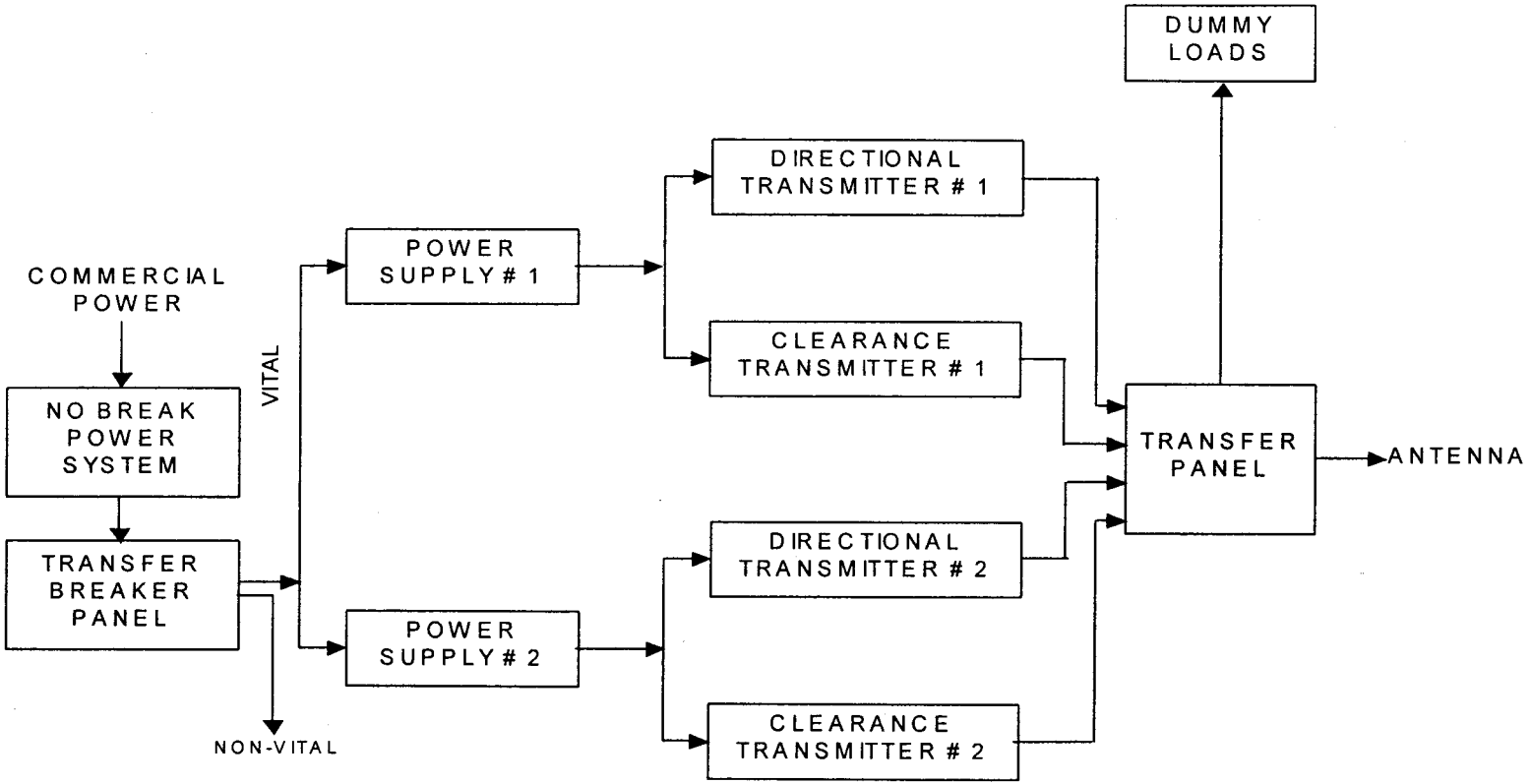


This breaks the product into natural and logical elements, becoming more detailed at each level down (for example, if the top level of the heirachy is a system, the next level down might be subsystem, the next level assemblies, and so on).

ANNEX F

(*Clause* 5.2)

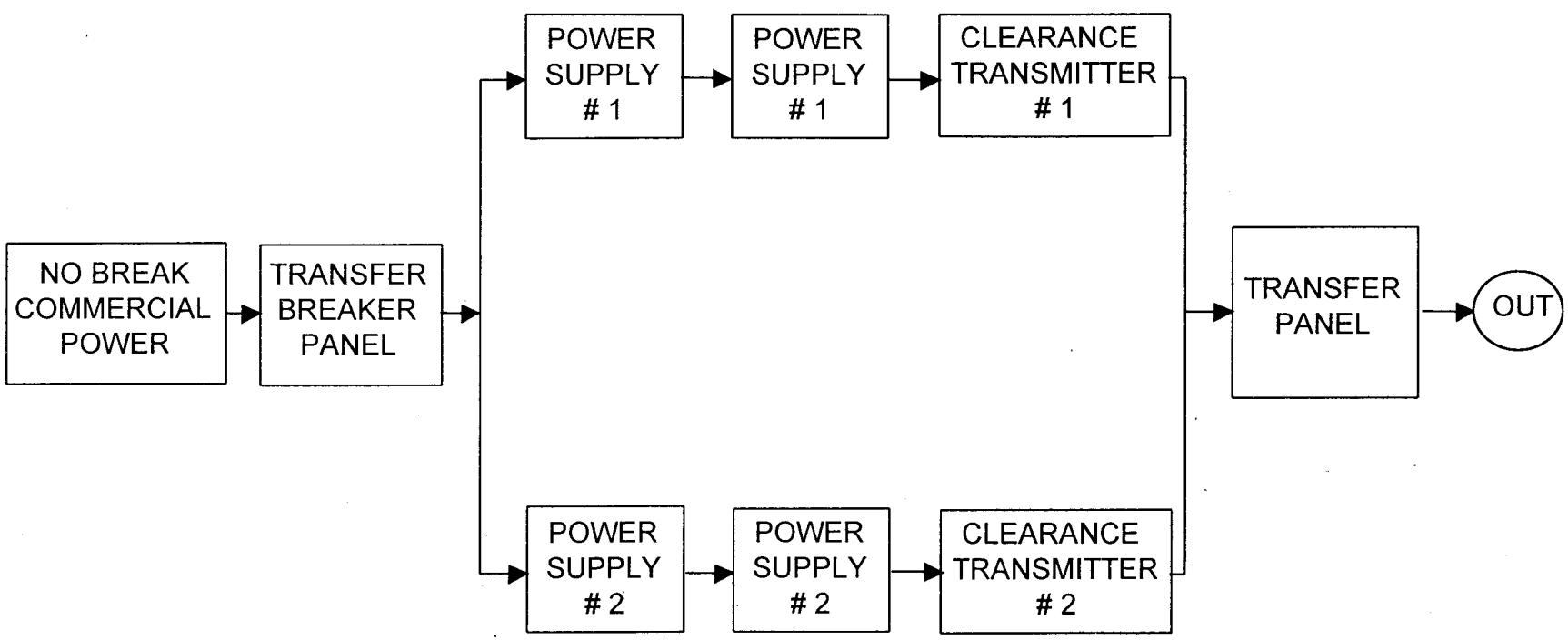
FUNCTIONAL BLOCK DIAGRAM



ANNEX G

(*Clause* 5.2)

RELIABILITY DIAGRAM



ANNEX H

(*Clause* 5.3)

POTENTIAL DESIGN/PROCESS FMEA

FMEA Number----------

--------System

Page -----of -----

--------Subsystem

--------Component---------- **Design Responsibility ----------** **Prepared By ----------**

Model Year(s)/Vehicle(s) ---------- **Key Date ----------** **FMEA Date (orig.)----------(Rev)----------**

Core Team ----------

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s) / Mechanism(s) of Failure	Occur	Current Design Controls Prevention	Current Design Controls Detection	Detec	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
													Actions taken	Sev	Occ	Det	RPN

ANNEX J

(*Clause* 5.4)

POTENTIAL DESIGN FMEA

--------System

--------Subsystem

--------Component----------

Model Year(s) /Vehicle(s) ----------

Core Team ----------

Design Responsibility ----------

Key Date ----------

FMEA Number---------

Page -----of ----------

Prepared By ----------

FMEA Date (orig.)----------(Rev)------

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s) / Mechanism(s) Of Failure	Occur	Current Design Controls -Prevention	Current Design Controls -Detection	Dec	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Action Results: Actions taken	Sev	Occ	Det	RPN
Front Door L.H. H8HX-0000-A • Ingress to and egress from vehicle Occupant • protection from w eather, noise, and side impact • Support anchorage for door hardw are including mirror, hinges, latch and w indow regulator	Corroded interior low er door panels	Deteriorated life of door leading to: • Unsatisfactory appearance due to rust through paint over time • Impaired function of interior door hardw are	7		Upper edge of protective wax application specified for inner door paints is too low	6		Vehicle general durability test veh. T-118 T-109 T-301	7	294	Add laboratory accelerated corrosion testing	A tate-Body Engrg 8X 09 30	Based on test results (Test No.1481) upper edge spec raised 125mm	7	2	2	28
			7		Insufficient wax thickness specified	4		Vehicle general durability testing as above	7	196	Add laboratory accelerated corrosion testing Conduct Design of Experiments (DOE) on wax thickness	Combine w/test for wax upper edge verification A tate-Body Engrg 9X 01 15	Test results (Test No.1481) show specified thickness is adequate. DOE show s 25% variation in specified thickness is acceptable.	7	2	2	28
			7		Inappropriate wax formulation specified	2		Physical and Chem. Lab test. Report No.1265	2	28	None						
• Provide proper surface for appearance items • Paint and soft trim			7		Entrapped air prevents w ax from entering	5		Design aid investigation w ith non-functioning spray head	8	280	Add team evaluation using production spray equipment and specified wax	Body Engrg & Assay Ops 8X 11 15	Based on test, 3 additional vent holes provided in affected areas	7	1	3	21
			7		Insufficient room betw een panels for spray head access	4		Draw ing evaluation of spray head access	4	112	Add team evaluation using design aid buck and spray head	Body Engrg & Assy Ops 8X 09 15	Evaluation show ed adequate access	7	1	1	7

ANNEX K

(Clauses 6 and 8)

POTENTIAL FMEA

FMEA Number---------

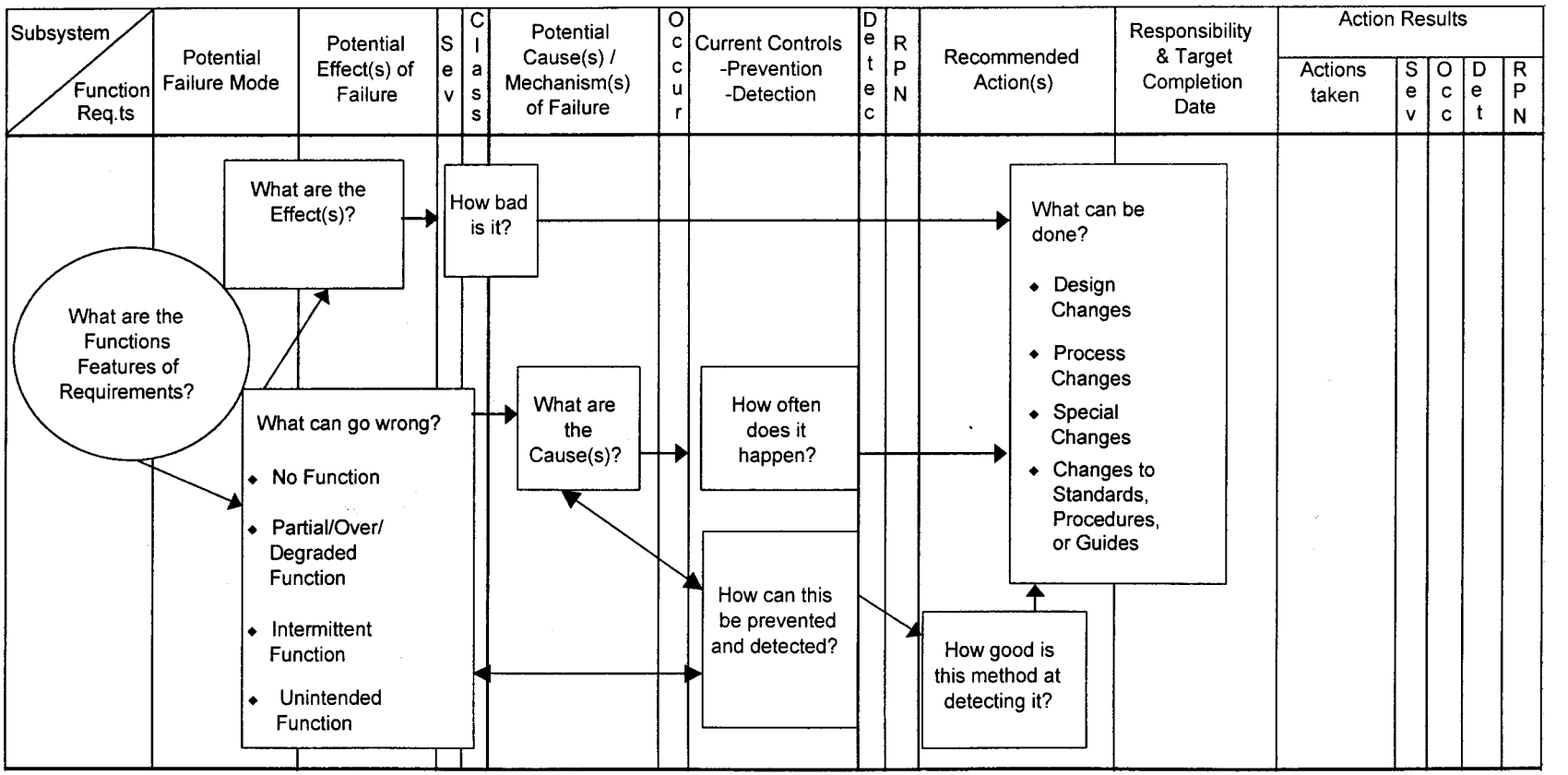
---------System

---------Subsystem **Page -----of———**

Machinery/System---------- **Design Responsibility ----------** **Prepared By ----------**

Model Year(s) /Programme(s) ---------- **Key Date ----------** **FMEA Date (orig.)----------(Rev)----------**

Core Team ----------



ANNEX L

(*Clause* 7.1)

POTENTIAL PROCESS FMEA

FMEA Number----------

Page -----of -----

ITEM---------- Process Responsibility ---------- Prepared By ----------

Model Year(s) /Vehicle(s) ---------- Key Date ---------- FMEA Date (orig.)----------(Rev)----------

Core Team ----------

Process function / Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s) / Mechanism(s) of Failure	occur	Current Process Controls -Prevention	Current Process Controls -Detection	Detec	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
													Actions taken	Sev	Occ	Det	RPN

ANNEX M

(*Clause* 7.1)

POTENTIAL PROCESS FMEA

FMEA Number———————

Page———— **of** ————

ITEM---------- **Process Responsibility** ---------- **Prepared By** ----------

Model Year(s) /Vehicle(s) ---------- **Key Date** ---------- **FMEA Date (orig.)**----------**(Rev)**----------

Core Team ----------

Process function / Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s)/ Mechanism(s) of Failure	Occur	Current Process Controls -Prevention	Current Process Controls -Detection	Detec	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Action Results: Actions taken	Sev	Occ	Det	RPN
Manual application of wax inside door	Insufficient wax coverage over specified surface	Deteriorated life of door leading to: • Unsatisfactory appearance due to rust through paint over time • Impaired function of interior door hardware	7		Manually inserted spray head not inserted far enough	8		Visual check each hour-1/shift for film thickness (depth meter) and coverage	5	280	Add positive depth stop to sprayer	MFG Engrg 9X 10 15	Stop added, sprayer checked on line	7	2	5	70
											Automate spraying	MFG Engrg 9X 12 15	Rejected due to complexity of different doors on same line				
To cover inner door, lower surfaces at minimum wax thickness to retard corrosion			7		Spray heads clogged • Viscosity too high • Temperature too low • Pressure too low	5	Test spray pattern at start-up and after idle periods, and preventive maintenance programme to clean	Visual check each hour-1/shift for film thickness (depth meter) and coverage	5	175	Use Design of Experiments (DOE) on viscosity *vs.* temperature *vs.* pressure	MFG Engrg 9X 10 01	Temp and press limits were determined and limit controls have been installed control charts show process is in control Cpk = 1.85	7	1	5	35
			7		Spray heads deformed due to impact	2	Preventive maintenance programmes to maintain heads	Visual check each hour-1/shift for film thickness (depth meter) and coverage	5	70	None						
			7		Spray time insufficient	8		Operator instructions and lot sampling(10 doors / shift) to check for coverage to check for coverage of critical areas	7	392	Install spray timer	Maintenance 9X 09 15	Automatic spray timer installed -operator starts spray, timer controls shut-off control charts show process is in control Cpk = 2.05	7	1	7	49

ANNEX N

(*Clause* 9)

FMEA TIMING IN THE PRODUCT DEVELOPMENT CYCLE

Product Development Cycle	System FMEA	Design FMEA	Process FMEA
Design Concept	Initiate		
Design Simulation	Complete*	Initiate	Initiate
Detailed Design		Update	
Prototype Test		Complete*	Update
Product Launch			Complete*
Field Usage	Update	Update	Update

* Since the FMEA is a living document, the term complete indicates the publication of the first iteration of the document and its release as input to the next level of FMEA to be performed or updated.

ANNEX P

(*Clause* 12)

DESIGN FMEA CHECKLIST

Customer or Internal Part No.....

	QUESTION	Yes	No	Comment/Action Required	Person Responsible	Due Date
1.	Was the System. FMEA and/or Design FMEA prepared using this standard?					
2.	Have historical campaign and warranty data been reviewed?					
3.	Have similar part Design FMEAs been considered?					
4.	Does the system FMEA and/or Design FMEA identify special characteristics?					
5.	Have design characteristics that affect high risk priority failure modes been identified?					
6.	Have appropriate corrective actions been assigned to high risk priority numbers?					
7.	Have appropriate corrective actions been assigned to high risk severity numbers?					
8.	Have risk priorities been revised when corrective actions have been completed and verified?					

Revision Date.....

Prepared By

ANNEX Q

(*Clause* 12)

PROCESS FMEA CHECKLIST

Customer or Internal Part No.....

	QUESTION	Yes	No	Comment / Action Required	Person Responsible	Due Date
1.	Was the Process FMEA prepared using this standard?					
2.	Have all operations affecting fit, function, durability, governmental regulations and safety been identified and listed sequentially ?					
3.	Were similar part FMEAs considered ?					
4.	Have historical campaign and warranty data been reviewed ?					
5.	Have appropriate corrective actions been planned or taken for high risk priority numbers ?					
6.	Have appropriate corrective actions been planned or taken for high severity numbers ?					
7.	Were risk priorities numbers revised when corrective action was completed ?					
8.	Were high severity numbers revised when a design change was completed ?					
9.	Do the effects consider the customer in terms of the subsequent operation, assembly and product ?					
10.	Was warranty information used as an aid in developing the process FMEA?					
11.	Were customer plant problems used as an aid in developing the process FMEA ?					
12.	Have the causes been described in terms of something that can be fixed or controlled ?					
13.	Where detection is the major factor, have provisions been made to control the cause prior to the next operation ?					

Revision Date.....

Prepared By

ANNEX R

(Foreword)

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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards : Monthly Additions'.

This Indian Standard has been developed from Doc : No. MSD 3 (166).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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